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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/665,847 | 09/19/2003 | C. Dominique Toran-Allerand | 0575/66236/JPW/AJM/DNS | 8389 |

7590 07/03/2006

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| EXAMINER | |
|---|---|
| JIANG, DONG | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/665,847 | TORAN-ALLERAND, C. DOMINIQUE | |
| | Examiner | Art Unit | |
| | Dong Jiang | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Currently, claims 1-41 are pending.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to an isolated estrogen receptor, classified in class 530, subclass 350.

II. Claims 3 and 4, drawn to a composition of matter comprising a lipid membrane, classified in class 435, subclass 7.2.

III. Claims 5-9, drawn to a method for determining the binding and the affinity of an agent to the receptor, classified in class 435, subclass 7.1.

IV. Claims 10-13, drawn to a method for determining an agonist or an antagonist of the receptor, classified in class 435, subclass 7.1.

V. Claims 14-16, drawn to a method for activating the MAP kinase pathway of a cell with 17α-estradiol, classified in class 435, subclass 7.21.

VI. Claims 17-22, drawn to a method for treating or delaying onset of a neurodegenerative disorder by administering 17α-estradiol, classified in class 514, subclass 182.

VII. Claims 23-27, drawn to a method for treating a neurodevelopmental disorder by administering 17α-estradiol, classified in class 514, subclass 182.

VIII. Claims 28-33, drawn to a method for treating a sexually dimorphic childhood disorder of cognition by administering 17α-estradiol, classified in class 514, subclass 182.

IX. Claims 34-36, drawn to a method for treating a uterine disorder by administering 17α-estradiol, classified in class 514, subclass 182.

X. Claims 37-39, drawn to a method for treating a pulmonary disorder by administering 17α-estradiol, classified in class 514, subclass 182.

XI. Claims 40 and 41, drawn to a composition of 17α-estradiol, and an article comprising same, classified in class 514, subclass 182.

The inventions are distinct, each from the other because:

The receptor polypeptide of Invention I is distinct from the lipid membrane composition of invention II because they are physically and functionally distinct chemical entities, and are for different uses. Also, neither is required for the manufacture of the other.

Invention I and inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating antibodies.

Invention I is distinct from and unrelated to inventions V-X, wherein the receptor polypeptide of Invention I can be neither made by nor used in the method of Inventions V-X, and wherein each does not require the other.

The receptor polypeptide of Invention I is distinct from and unrelated to the composition of Invention XI because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other.

Invention II is distinct from and unrelated to inventions III-X, wherein the receptor polypeptide of Invention I can be neither made by nor used in the method of Inventions III-X, and wherein each does not require the other.

The lipid membrane composition of Invention II is distinct from and unrelated to the composition of Invention XI because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other.

Inventions III-X are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, and each does not require the other, such that they require separate searches. Note, although inventions VI-X are drawn to methods of treatment using the composition of 17a-estradiol, they are distinct, each from each other, because they are the methods of treating

different medical conditions, which have distinct pathological causes, involve distinct patient populations, have distinct clinical manifestations, distinct features in progress and prognosis, and require different therapies. Therefore, each group requires a separate search of the prior art.

Inventions III-V are distinct from and unrelated to invention XI, wherein the composition of Invention XI can be neither made by nor used in the method of Inventions III-V, and wherein each does not require the other.

Invention XI and inventions VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for in vitro assays of its receptor activity.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory Information***

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/22/06